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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,357	11/27/2001	Malcolm L. Gefter	PPI-105	1918
959	7590	11/24/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			NICHOLS, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,357	GEFTER ET AL.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 September 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 74-76 and 79-98 is/are pending in the application.
 - 4a) Of the above claim(s) 79-97 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 74-76 and 98 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 74-76 and 79-96 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 September 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 23 September 2004 has been received and entered in full.
2. Newly submitted claims 79-97 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant has copied subject matter from cancelled, non-elected claims 1-73 and incorporated them as dependent claims in the elected invention. Said subject matter was not elected in the response to the Restriction Requirement mailed 14 January 2004.
3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 79-97 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

5. The Objection to the Specification as set forth in the previous Office Action (23 April 2004) is hereby *withdrawn* in view of Applicant's amendments (23 September 2004).

Maintained Objections And/Or Rejections

6. Claims 74-76 and 98 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method for preparing A β (16-30)-hFc*, does not reasonably provide enablement for *preparing any therapeutic agents, any as of yet unspecified peptide-target protein combinations, or any agents containing D-amino acids*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make** or **use** the invention commensurate in scope with these claims for the reasons as set forth at pp. 3-9 ¶5-14 in the previous Office Action (23 April 2004).

7. Applicant traversed the rejection of the claims on the following grounds. Applicant argues that ample evidence, working examples for the claimed invention. In addition, the methods for identifying peptides that have the ability to bind a target molecule are well known in the art. Further the composition and nature of a “linker” is taught in the Specification.

8. Applicant’s arguments have been taken into consideration and are not found persuasive for the following reasons. The claims as instantly presented represent an invitation to experiment where one would discover a therapeutic agents represented by the formula I-L-P’. While therapeutic agents represented by the formula I-L-P’ may constitute a fecund ground for investigation, the CAFC ruled in *Genentech Inc. v. Novo Nordisk A/S* (CA FC) **42 USPQ2d 1001** (1997) that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Citing *Brenner v. Manson*, **383 U.S. 519, 536, 148 USPQ 689, 696** (1966) (stating, in context of the utility requirement, that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”). Therefore the CFAC stated that tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic

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claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in the instant specification with respect to the any therapeutic agents represented by the formula I-L-P' which in turns has any therapeutic activity for any given disease, disorder, or injury save for A β (16-30)-hFc.

9. The Examiner notes that the Specification teaches the manufacture of a fusion protein comprising A β (16-30) fused to the N-terminus of a peptide consisting of the human IgG1 Fc domain and hinge region (A β (16-30)-hFc) domain (Example 8). A β (16-30)-hFc was administered to a mouse transgenic for both the Swedish mutation of amyloid precursor protein (APP) and presenilin M146L by direct infusion into the cerebral cortex in one hemisphere (Example 9). The mouse was scarified and the amount of amyloid in brain sections was determined by Thioflavin S staining. The plaque burden at the site of infusion was significantly decreased compared to the contra-lateral control hemisphere (Figure 10).

10. Thus the specification of the instant application fails to provide adequate guidance for one of skill in the art to overcome the unpredictability and challenges of applying results from *suggestion* to the manufacture and use of therapeutic agent other than A β (16-30)-hFc.

11. Claims 74-76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention the reasons as set forth at pp. 9-12 ¶¶15-21 in the previous Office Action (23 April 2004).

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12. Applicant traverses this rejection asserting that the therapeutic agents represented by the formula I-L-P' is disclosed in the Specification. Applicant's arguments have been taken into consideration and are not found persuasive because Applicant has only disclosed a desired outcome and not has sufficiently described the desired therapeutic agent. MPEP §2145 clearly states that attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection (MPEP § 2129 and §2144.03). Furthermore, the arguments of counsel cannot take the place of evidence in the record. In the instant case the Applicant is asserting possession of therapeutic agents represented by the formula I-L-P' while no data, information, or teaching supports possession of any therapeutic agents represented by the formula I-L-P' in the instant Specification {see *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.") and MPEP § 716.01(c)}.

13. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. The instant claims are most analogous to *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004] wherein a claim consisted of a "reach-through-claim" where the desired properties of the product were known but the product was not disclosed. In the instant

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application, claim 74 is a “reach-through-claim” where therapeutic agents represented by the formula I-L-P’ have known desired properties but the product itself is not has not been disclosed.

14. Furthermore, the method as instantly presented is inadequate to identify the desired product.

15. Therefore the full breadth of the claim fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

Summary

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
November 17, 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER